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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,500	08/01/2001	Nobuhiko Ogura	Q65512	3311

7590 11/19/2003

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EXAMINER

SIEW, JEFFREY

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/918,500	OGURA, NOBUHIKO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey Siew	1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-41<sup>43</sup> and 45-75 is/are rejected.
- 7) ☐ Claim(s) 42,44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,5,7,9,11,13,17,19,22,25,28, 31,34,37,40,43,46,49,52,55,58,61,64 & 66-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) The phrase “and the like” renders claims 2,5,7,9,11,13,17,19,22,25,28, 31,34,37,40,43,46,49,52,55,58,61,64 & 66-75 indefinite. It is unclear as to what criteria the phrase “and the like” is measured. The metes and bounds of the scope of the phrase is unclear.

The response states that one of ordinary skill in the art would understand the scope of the language of the claim. As the terms “and the like” follow such varied terms as sequence, length and composition, it would be unclear to one of ordinary skill in the art to determine what criteria would fall within the scope of the claims. The metes and bounds of the claim are indeterminate. It is recommended the phrase be deleted.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,6-11,14-20,57-65,70-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter et al (US5,837,194 Nov. 17 , 1998)

Potter teach a method and apparatus for detecting chemiluminescent assay in which a perforated plate is used with nylon filter containing labeled probe (see whole doc. esp. col. 3 lines 30-45 & Figures 1 & 2A). They teach using 96 sample plates (see col. 5 line 27). They teach the use of black grid disposition for adsorption of laterally emitted light. They teach irradiating and detection (see col. 5 & 6). They also teach using radioactive probes and radioactive detection (see col. 8 lines 2-20).

The response filed 8/26/03 regarding the Potter reference has been fully considered and deemed not persuasive. The response states that Potter teach a nylon plate and therefore high density spots cannot be formed at high density of 200 to 300um. The claims do recite high density. Potter also do teach a black grid disposition for adsorption of emitted light. The new limitation of charging would be met by the Potter's irradiation. The rejection is maintained.

(c) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b)

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only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1,2, 5-13,18,19,21,22,24,25,27,28,30,31,36,37, 45,46,48,49,51,52,54,55 are rejected under 35 U.S.C. 102(e) as being anticipated by Pham et al (US6,426,050 July 30, 2002).

Pham et al teach a biochemical analysis unit comprising a substrate made of material capable of attenuating light energy (see col. 3 lines 47-52) and formed with a plurality of holes (see col. 2 lines 40-45) and plurality of absorptive regions formed in region in hole (see whole doc. esp. abstract esp. col. 5 lines 24-50). They teach that device is suite for fluorescent based assays (see col.1 line 57). They teach the support has regions which to grip the whole plate (see figure 14). They teach that 10,000 wells may be used (see col. 2 line 45). They teach diameter size of well of .2mm (see col. 3 line 26) which would equate to 100 wells per cm<sup>2</sup>. They teach that the plate may be made of polymerase such as polystyrene and cycloolefins which would possess a degree of flexibility (see col.1 line 63). They teach opaque material to prevent transmittance of light greater than 99% (see col. 3 lines 53). The teach coatings of wells such as derivatized ionization techniques (see col. 5 lines 29). They also teach that wells may contain pigments to darken light to help reduce background fluorescence (see col. 3 lines 55-66). They teach chemical moieties in binding pairs include nucleic acids and proteins.

The response filed 8/26/03 regarding the Pham reference has been fully considered and deemed not persuasive. The response states that Pham do not teach high transmittance portion is not formed in the well. However, the response admits that Pham's high transmittance is provided at the bottom of a well. Pham's wells therefore meet the limitation of being formed in the well.

Moreover, the response states that Pham do not teach high density. The claims do not recite such a limitation. The new limitation of charging would be met by the Pham's irradiation. The rejection is maintained.

4. Claims 1,2,3,8,9, 18,19,21,22,70-72,74 & 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Vuong (US6,448,089 Sept. 10, 2002).

Vuong et al teach a biochemical analysis method comprising preparing a biochemical analysis unit comprising by spotting specific binding substances in an plurality of absorptive regions in holes (see col.4 lines 26 teaching microtiter plates ) and specifically binding substance derived from living organisms (see col. 13 lines 34-55) and labeled with fluorescent substance (see col.11 lines42; col12 lines 20-65)., irradiating (see Figure 3, col.7 lines 64-col. 8 lines 4), and photoelectrically detecting (see whole doc. esp. abstract & col. 8 lines 4-44).

The response filed 8/26/03 regarding the Vuong reference has been fully considered and deemed not persuasive. The response states that Vuong do not teach charging. The new limitation of charging would be met by the Vuong's irradiation in the photoelectrical detection. The rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33,34,39 & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pham et al (US6,426,050 July 30, 2002).

Pham et al teach a biochemical analysis unit comprising a substrate made of material capable of attenuating light energy (see col. 3 lines 47-52) and formed with a plurality of holes (see col. 2 lines 40-45) and plurality of absorptive regions formed in region in hole (see whole doc. esp. abstract esp. col. 5 lines 24-50). They teach that device is suite for fluorescent based assays (see col.1 line 57). They teach the support has regions which to grip the whole plate (see figure 14). They teach that 10,000 wells may be used (see col. 2 line 45). They teach diameter size of well of .2mm (see col. 3 line 26) which would equate to 100 wells per cm<sup>2</sup>. They teach that the plate may be made of polymerase such as polystyrene and cycloolefins which would possess a degree of flexibility (see col.1 line 63). They teach opaque material to prevent transmittance of light greater than 99% (see col. 3 lines 53). The teach coatings of wells such as derivatized ionization techniques (see col. 5 lines29). They also teach that wells may contain pigments to darken light to help reduce background fluorescence (see col. 3 lines 55-66). They teach chemical moieties in binding pairs include nucleic acids and proteins

Pham et al do not explicitly teach the claimed hole size of 0.1mm<sup>2</sup> and density of at least 10000 per cm<sup>2</sup>.

One of ordinary skill in the art would have been motivated to further decrease the hole size and thereby increase density as taught by Pham et al in order to increase the reaction samples in the plate. Pham et al state that larger number of wells or increased well density is

easily accomplished using their methods(see col.2 lines 38-40). It would have been prima facie obvious to apply Pham et al's teaching to optimize the hole density by decreasing hole size in order to increase the number reactions that would be performed per plate.

6. Claims 45-53,55 & 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter et al (US5,837,194 Nov. 17 , 1998) in view of Warner et al (US4,728,792 March 1, 1988).

The teachings of Potter et al are described previously.

Potter et al do not explicitly recite the 1/5, 1/10 or 1/100 decreases in light to neighboring regions.

Warner et al teach the sorption sheet to sorb cross-talking photons (see whole doc. )

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Warner et al's sorption sheet to maximally decrease the cross talk photons between sample regions in Potter et al's device in order to prevent background noise. Potter et al even suggest using the sorption sheet of Warner et al (see col. 5 line 24). It would have been prima facie obvious to apply Warner et al's and optimize the decrease the radiation cross talk between samples in Potter et al's device in order to eliminate background noise during detection.

The response filed 8/26/03 regarding the Warner reference has been fully considered and deemed not persuasive. The response states that Warner material is difficult to prevent photon release. However, Warner et al specifically teach that the sheets adsorb cross talking photons to allow for individual monitoring. It would be expected that Warner et al' sorption sheet would sufficiently block light in Potter et al's method. The rejection is maintained.



7. Claims 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter et al, in view of Ogura (US6,130,440 Oct. 10, 2000)

The teachings of Potter et al are described previously.

Potter et al do not teach stimuable phosphor sheet.

Ogura teach the stimuable phosphor sheet to detect biochemical images (see whole doc. esp. abs & col. 2 lines 15-60)

One of ordinary skill in the art at the time the invention was made would have been motivated to apply stimuable phosphor sheet in order to detect light transmissions of either Potter et al's biochemical device. Ogura et al state that the benefits of eliminating chemical processing (see col.2 lines 11). It would have been prima facie obvious to apply Ogura et al's stimuable phosphor imaging sheet in Potter et al's device in order to detect bound probes by eliminating the chemical processing.

8. Claims 23,26,29,32,35,38,41 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter et al (US5,837,194 Nov. 17, 1998) in view of Pham et al

The teachings of Potter et al are described previously.

Potter et al do not teach regions of 10,000, holes of less than  $0.1\text{mm}^2$  and density of 10,000 per  $\text{cm}^2$ .

The teachings and suggestions of Pham et al are described previously. Briefly, Pham et al teach a biochemical analysis unit comprising a substrate made of material capable of attenuating light energy (see col. 3 lines 47-52) and formed with a plurality of holes (see col. 2 lines 40-45) and plurality of absorptive regions formed in region in hole (see whole doc. esp. abstract esp. col.

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5 lines 24-50). They teach that device is suite for fluorescent based assays (see col.1 line 57). They teach the support has regions which to grip the whole plate (see figure 14). They teach that 10,000 wells may be used (see col. 2 line 45). They teach diameter size of well of .2mm (see col. 3 line 26) which would equate to 100 wells per cm<sup>2</sup>. They teach that the plate may be made of polymerase such as polystyrene and cycloolefins which would possess a degree of flexibility (see col.1 line 63)They also teach that wells may contain pigments to darken light to help reduce background fluorescence (see col. 3 lines 55-66). They teach chemical moieties in binding pairs include nucleic acids and proteins. Pham et al state that larger number of wells or increased well density is easily accomplished using their methods(see col.2 lines 38-40).

One of ordinary skill in the art would have been motivated to apply Pham et al's teachings of increased number and density of reaction regions to Potter et al in order to increase the number of reactions performed per plate. It would have been prima facie obvious to apply Pham et al's method of increase plurality of reaction holes to Potter et al's reaction sites in perforated holes in order to increase the number reactions performed in a single plate.

## SUMMARY

9. Claims 42 & 44 are objected to for depending on rejected claim. Claim 43 is rejected under 112 second paragraph but free of the prior art. There is no prior art that teach or suggest the biochemical analysis unit with density of holes at 10,000 or more per cm<sup>2</sup>.

## **CONCLUSION**

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
JEFFREY SIEW  
PRIMARY EXAMINER

February 21, 2003